

Conway Hearing Aid Center

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September 21, 2000

Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, SW
Room 615F
Washington, D.C. 20201

Dear Secretary Shalala:

I am a small business owner in Conway, Arkansas, providing hearing health care services to the area's hearing impaired.

I am very concerned with reports that the Food and Drug Administration has reportedly sent to you a proposal for revising the current regulations governing the dispensing of hearing aids in this country that would dramatically increase the cost of hearing health care services and restrict access to hearing health care providers. Please stop and carefully consider the impact that this proposed rule will have on the nation's hearing impaired and on the nation's small business hearing aid specialists. In particular, please ensure that any proposed rule meets the obligations of the Small Business Regulatory Enforcement Fairness Act.

Hearing health care providers like me have been working with the FDA since 1993, to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new administration, FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like me from the marketplace. FDA favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any justification.

Hearing aids are safe and effective medical devices. Please don't let the FDA put forth a ruling that would create barriers for the millions of hearing impaired who need hearing health care services.

Sincerely,



Lois H. Brown, BC-HIS

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*Donna Shakala
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